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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, vs. JAMES AMMON a.k.a. JAMES SOTO; ECO APOTHECARY, LLC; and ECO PHARMACY OF SALT LAKE CITY, LLC, Defendants.	**COMPLAINT FOR DAMAGES, PENALTIES, AND INJUNCTIVE RELIEF** Civil No. 2:20-cv-00126-DBB Judge David B. Barlow

Plaintiff, the United States of America, alleges as follows:

1. The United States of America brings this action against James Ammon, Eco Apothecary, LLC, and Eco Pharmacy of Salt Lake City LLC seeking civil monetary penalties and injunctive relief for Defendants' violations of the Controlled Substances Act, 21 U.S.C. § 801, et seq. (the "CSA") and its implementing regulations, 21 C.F.R. § 1301, et seq. The United States also seeks to recover monies that Defendants caused the Medicare and Medicaid programs to pay for prescriptions that were not valid, not used for a medically accepted indication, lacked a legitimate medical purpose, were paid for yet not dispensed, and/or were dispensed by an unlicensed pharmacy all in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, et seq.

2. The United States also seeks to recover treble damages and civil penalties arising from Defendants' violations of the FCA.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. §§ 842(c)(1)(A) and 882(a), 28 U.S.C. §§ 1331, 1345, 1355, and 1367(a), and 31 U.S.C. §§ 3730(a) and 3732(b).

4. Venue is proper in the District of Utah pursuant to 21 U.S.C. § 843(f)(2), 28 U.S.C. §§ 1391(b), 1395(a), and 31 U.S.C. § 3730(a) and 3732(b), because the Defendants are located, reside, do business, or committed the acts at issue in this district.

PARTIES

5. Plaintiff United States of America brings this action on behalf of the Department of Justice, as delegated to the Drug Enforcement Administration ("DEA"), which regulates the distribution of controlled substances under the authority of the CSA, and on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), which administer the Medicare and Medicaid programs.

6. Defendant Eco Apothecary, LLC is a limited liability company registered in the State of Delaware. At times relevant to this Complaint, Eco Apothecary was licensed by the State of Utah to operate as a Class B closed door pharmacy, license number 10581590. Its license expired on September 30, 2019. Eco Apothecary is currently registered with the United States Drug Enforcement Agency ("DEA") as a retail pharmacy with privileges to fill prescriptions and dispense schedule II through V controlled substances. Eco Apothecary's DEA registration number is FE72884975. Eco Apothecary was first registered with the DEA on

January 10, 2018. Eco Apothecary's physical location and principal place of business is or was 3702 South State Street, Suite 117, Salt Lake City, Utah. Eco Apothecary's national provider number is 1568973055.

7. Defendant Eco Pharmacy of Salt Lake City, LLC ("Eco Pharmacy") is a limited liability company registered in the State of Texas. At times relevant to this Complaint, Eco Pharmacy was licensed by the State of Utah to operate a Class A retail pharmacy to fill prescriptions for and dispense controlled substances, license number 9301773-1703. Eco Pharmacy's license to operate a pharmacy issued by the State of Utah expired on September 30, 2019. Eco Pharmacy surrendered its DEA registration, number FE5775260, on October 17, 2018. Eco Pharmacy's physical location and principal place of business is or was 12523 Creek Meadow Road #105, Riverton, Utah 84065. Eco Pharmacy's national provider number is 1093228645.

8. Defendant James Ammon is and was the owner, manager, pharmacist, and pharmacist-in-charge of Eco Apothecary and is licensed to practice pharmacy by the State of Utah. Mr. Ammon was the manager and pharmacist at Eco Pharmacy. Mr. Ammon was licensed by the State of Utah as a pharmacist on July 23, 1997. Mr. Ammon was licensed by the State of Wyoming on October 11, 2005, and the State of Nevada on September 24, 2015. Mr. Ammon's Utah and Nevada pharmacy licenses remain valid. At all times relevant to this Complaint, Ammon was acting within the scope of his employment and duties as an agent, servant, and employee of, and in furtherance of the business interests of Eco Pharmacy and Eco Apothecary. Ammon resides in Salt Lake City, Utah.

9. Mr. Ammon began using a new name or changed his name from James Vaughn Ammon to James Vaughn Soto on around June 2019.

THE CONTROLLED SUBSTANCES ACT

10. The CSA was enacted in 1970 to deter "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances [which] have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2).

11. The Act establishes a classification system for all controlled substances, including those contained in prescription medications, based upon the potential for abuse, dependence profile, and medicinal value of the drugs. *See* 21 U.S.C. § 812(b). Schedule I substances have a high potential for abuse, have no currently accepted medical use in the United States, and lack accepted safety when used under medical supervision. Except for research, these substances are essentially contraband. Schedule II substances have a high potential for abuse, but also have a currently-accepted medical use in treatment in the United States. If abused, Schedule II substances can lead to severe psychological or physical dependence. Schedule III substances have a potential for abuse that is less than that of Schedule I and II substances, have a currently-accepted medical use in treatment in the United States, and, if abused, can lead to moderate or low physical dependence, or high psychological dependence. Schedule IV substances have a low potential for abuse relative to Schedule III substances, have a currently accepted medical use in the United States, and, if abused, can lead to limited physical or psychological dependence, relative to Schedule III substances. Schedule V substances have a low potential for abuse relative to Schedule IV substances, have a currently accepted medical use in the United States, and, if

abused, may lead to limited physical or psychological dependence relative to Schedule IV substances.

12. The CSA authorizes the DEA to regulate controlled substances and to register handlers of controlled substances ("registrants"), thereby creating a "closed" system of distribution that "provides the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. Rep. No. 91-1444, 91st Cong., 2nd Sess. (1970), reprinted in 1970 U.S.C.A.A.N. 4566, 4571-4572.

13. The CSA requires those who dispense controlled substances to register with the DEA. *See* 21 U.S.C. § 822(a)(2) & 21 C.F.R. § 1301.11. Pharmacies that register may only dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with" the CSA. 21 U.S.C. § 822(b).

14. The CSA makes it unlawful for those who dispense controlled substances "to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice" required by the CSA. 21 U.S.C. § 842(a)(5).

15. The CSA and regulations thereunder are intended to serve as a vehicle for reducing the misappropriation or redirection of controlled substances from their intended, legitimate recipients into the hands of those who would abuse them for other than legitimate medical purposes, or to persons who would distribute drugs to such abusers. This phenomenon is more commonly known as "drug diversion."

16. Diversion of controlled substances and other prescription drugs is a major health problem in the United States. For example, the CDC reported a 30% increase in emergency department visits for opioid overdoses in the United States from July 2016 through September

2017. The CDC also reports that from 1999 to 2017, more than 702,000 people have died from a drug overdose. In 2017 alone more than 70,000 people died from drug overdoses, making it the leading cause of injury-related deaths in the United States. Of those deaths, almost 68% involved a prescription of illicit opioid. The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that of the estimated 1,244,872 emergency department visits involving nonmedical use of pharmaceuticals in 2011, 366,181 (29 percent) involved narcotic pain relievers. An additional 138,130 visits involved unspecified opiates or opioids. Emergency department visits involving oxycodone---the most common narcotic pain reliever among visits involving nonmedical use of pharmaceuticals---increased from 2005 to 2009. In 2017, on average 91 Americans died every day due to opioid overdose. In many cases, abuse of prescription drugs that had been diverted from pharmacies has caused serious bodily injury and even death.

17. The record-keeping and reporting provisions of the CSA are intended to minimize diversion of these dangerous drugs by implementing a "closed" system of distribution. For example, 21 U.S.C. § 827 and 21 C.F.R. §§ 1304.03, 1304.04, 1304.11, 1304.21, and 1304.22 require DEA registrants, such as the defendants, to make and keep a complete and accurate record of all controlled substances received, sold, delivered, or otherwise disposed of, including controlled substances returned by a customer. These records must be kept, for at least two (2) years, and be available for inspection and copying by officers or employees of the United States authorized by the Attorney General. These record-keeping requirements allow both the registrant and the government to monitor the use of controlled substances and aid in detecting and

impeding efforts to divert and misuse controlled substances. Among the records required to be kept are:

A. Order forms DEA-222: triplicate forms required by DEA that document the distribution and receipt of Schedule I and Schedule II controlled substances. Pharmacies are required to retain Copy 3 of the DEA-222 upon which the number of containers received and date of receipt must be recorded. Copy 1 is retained by the supplier (distributor) and Copy 2 is sent by the supplier to the DEA;

B. Schedule II prescriptions, e.g., Oxycodone products including OxyContin, which have to be maintained separately from all other records; and

C. Schedule III-V prescriptions.

D. An inventory of all controlled substances on hand when the registrant first engages in the distribution or dispensing of controlled substances, and every second year thereafter.

E. An inventory maintained current of each controlled substance received, sold, delivered or otherwise disposed of.

18. The CSA and its implementing regulations also require that, with exceptions not relevant here, pharmacies such as those operated by the Defendants, dispense Schedule II-V controlled substances pursuant to valid prescriptions only:

A. Schedule II prescriptions: "except when dispensed directly by a practitioner . . . no controlled substance in Schedule II . . . may be dispensed without the written prescription of a practitioner . . . " 21 U.S.C. § 829(a).

B. Schedule III and IV prescriptions: "except when dispensed directly by a practitioner . . . no controlled substance . . . may be dispensed without a written or oral prescription of a practitioner . . ." 21 U.S.C. § 829(b).

C. To be valid for purposes of the CSA, a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his medical practice." 21 C.F.R. § 1306.04(a). A "corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

19. Defendants have violated the following provisions of the CSA: 21 U.S.C. §§ 842(a)(1); 842(a)(5); 843(a)(4); and 843(a)(2).

20. 21 U.S.C. § 842(a)(1) provides that it is unlawful for a person "to distribute or dispense a controlled substance . . . without the [valid] prescription of a practitioner," as set forth in 21 U.S.C. § 829.

21. 21 U.S.C. § 842(a)(5) provides that it is unlawful for any person "to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information" required under 21 U.S.C. §§ 801-971.

22. 21 U.S.C. § 843(a)(2) provides that it is unlawful for any person to knowingly or intentionally "use in the course of manufacture, distribution, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person."

23. 21 U.S.C. § 843(a)(4) provides that it is "unlawful for any person knowingly or intentionally--(A) to furnish false or fraudulent material information in, or omit any material

information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter, or (B) to present false or fraudulent identification where the person is receiving or purchasing a listed chemical and the person is required to present identification under section 830(a) of this title; . . .”

24. Recognizing the vital importance of properly accounting for all controlled substances, Congress authorized the assessment of fines and/or penalties of up to $64,820 per violation of Section 842(a)(1) and $15,040 per violation of Section 842(a)(5). 28 C.F.R. § 85.5 (adjustments to penalties for violations occurring after November 2, 2015).

25. Additionally, courts can impose injunctive relief to restrain violations of Sections 842 and 843 of the Controlled Substances Act. *See* 21 U.S.C. § 843(f).

THE FALSE CLAIMS ACT

26. The FCA provides that a person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” is liable to the United States for statutory damages and such penalties as are allowed by law. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

27. The FCA defines knowing and knowingly to mean “that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. Knowingly “require[s] no proof of specific intent to defraud[.]” 31 U.S.C. § 3729(b)(1).

28. The FCA provides penalties of up to three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of between $11,181 and $22,363 for each violation. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5.

THE MEDICARE PROGRAM

29. Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

30. The Medicare program consists of four parts: A, B, C, and D. Defendants submitted, or caused to be submitted, claims under Medicare Part D.

31. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

32. Part D coverage is not provided within the traditional Medicare program, and unlike traditional fee-for-service Medicare, Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan "Sponsors" to administer prescription drug plans.

33. Part D benefits are delivered by a Part D Plan Sponsor, which is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-inclusive Care for the Elderly (PACE)

organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

34. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D Plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary.

35. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

36. Each time a beneficiary fills a prescription under Medicare Part D, an MA-PD or PDP sponsor must submit a summary record called the PDE record to CMS. PDE records are not the same as individual drug claim transactions but are summary extracts using CMS-defined standard fields. CMS stores the PDE records submitted by MA-PD and PDP sponsors in the Integrated Data Repository (IDR). MA-PD and PDP sponsors submit an original PDE record and may either adjust or delete PDE records submitted to CMS within the designated schedule.

37. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. The data contained in PDEs are data related to payment of claims. The Integrated Data Repository ("IDR") process date is the date when the PDE is transmitted to CMS, such that CMS is informed of the PDE by the Part D Plan Sponsor.

38. In addition, CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. *See*

"Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

39. Under the Medicare Part D Program, the Centers for Medicare & Medicaid Services (CMS) makes payments to Medicare Advantage Prescription Drug Plan (MA-PD) and stand-alone Prescription Drug Plan (PDP) sponsors on a monthly basis through estimated subsidy payments and, if required, at year-end as a result of the payment reconciliation process. The payment reconciliation process compares estimated subsidy payments made to plan sponsors throughout the year with the cost data submitted by MA-PD and PDP sponsors through prescription drug event (PDE) records and Direct or Indirect Remuneration (DIR) data to determine any residual payments required by CMS to MA-PD and PDP sponsors or by MA-PD and PDP sponsors to CMS. The reconciliation process relies on four major data sources: the sum of payments made to plan sponsors throughout the year, final updated plan enrollment, PDE records from MA-PD and PDP sponsors, and DIR.

40. CMS's prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

41. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

42. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies ("LICS") and are documented and reconciled using PDE data submitted to CMS.

43. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. See 42 C.F.R. §§ 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for correcting submitted PDE data they determine are erroneous. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" at 4 (April 27, 2006).

44. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records.

45. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws, regulations, as well as CMS instructions.

46. By statute, all contracts between a Part D Plan Sponsor and HHS must include a provision whereby the Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

47. Medicare Part D Plan Sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 505(h)(1).

48. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the CSA. 42 C.F.R. § 423.505(i)(4)(iv).

49. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to the payment. This provision, entitled "Certification of data that determine payments," provides in relevant part, as follows:

> (1) General Rule. As a condition for receiving a monthly payment . . . the Part D plan an individual delegated the authority to sign on behalf of one of these officers, . . . must request payment under the contract on a document that certifies (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of all data related to payment.
> . . .
> (2) [Part D Sponsor] Certification of Claims Data: The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information and belief) that the claims data it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1) & (3) (emphasis added).

50. All approved Part D Plan Sponsors who received payment under Medicare Part D in benefit years relevant to this case submitted the required attestations for data submitted that related to payment. 42 C.F.R. § 423.505(k).

51. The "Certification of data that determines payments" provision of the applicable regulation further provides: "[i]f the claims data are generated by a related entity, contractor, or

subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

52. Compliance with the requirement that PDE data submitted by the Plan Sponsor is "true, accurate, and complete," based on best knowledge, information and belief, is a condition of payment to the Plan Sponsor under the Medicare Part D Program. *Id.* Compliance is also material to payment.

53. Medicare only covers drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. §§ 1395w-102(e)(1) & (e)(4); 42 U.S.C. §§ 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

54. PDEs submitted to Medicare for drugs that do not have a medically accepted indication do not contain accurate, complete and truthful information about all data related to payment.

55. Medicare only covers drugs that are dispensed upon a prescription. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.100. A "Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A valid prescription must comply "with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

56. Part D plans may also exclude drugs from payment if the drugs are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body part. 42 U.S.C. § 1395w-102(e)(3) (incorporating by reference 42 U.S.C. § 1395y(a)).

57. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not for "medically accepted indications" and are therefore not covered Medicare Part D drugs. 32 U.S.C. § 1395w(e)(1).

58. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as recreational use, are not "valid prescriptions" and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 423.104(h).

59. PDEs submitted to Medicare for controlled substances that are dispensed when not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice do not contain accurate, complete and truthful information about all data related to payment.

60. Compliance with federal and State of Utah requirements relating to pharmacies' dispensing of controlled substances was and remains material to Medicare's decision to pay the Defendants' claims for reimbursement of controlled substances. Compliance with these requirements is central to the Medicare Part D benefit and is a condition of these medications being covered by Medicare.

61. The government routinely denies payment for medications, or seeks to recoup payments already made, when such prescriptions are not issued or dispensed for a legitimate medical purpose in the usual course of professional practice. For example:

A. The United States Department of Justice ("DOJ") has litigated or settled numerous actions where it was alleged that medical providers and pharmacies submitted claims for controlled substance medications to Medicare that lacked a valid prescription, were not for a legitimate medical purpose and lacked a medically accepted indication, or that did not comply with State law. *See*, e.g., https://www.justice.gov/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations (detailing $1.45 million settlement resolving allegations of improper billing for painkillers, including opioids, and including a nurse practitioner's surrender of her DEA registration); *United States ex rel. Norris v. Florence*, Civ. Action No. 2:13-cv-00035 (M.D. Tenn.) (ongoing FCA litigation against a physician for causing the submission of false claims by pharmacies for controlled substances that were not for a legitimate medical purpose); https://www.justice.gov/opa/pr/long-term-care-pharmacy-pay-315-million-settle-lawsuit-alleging-violations-controlled (Pharmerica CSA and FCA settlement for improper dispensing of and billing Medicare for unlawfully dispensed prescriptions).

B. The United States has also filed the present action which if successful would result in stopping further improper Medicare claims for improperly filled prescriptions by Defendants.

C. The HHS Secretary's declaration in October 2017 that the opioid epidemic is a national public health emergency under federal law reflects the United States' stance to deny payment for improperly dispensed controlled substances.

62. Accordingly, a reasonable person would know that Medicare would not pay for Part D claims submitted to Medicare if it knew that the prescriptions at issues were invalid, the pharmacy or pharmacist did not comply with state law, and/or the prescriptions themselves

lacked a legitimate medical purpose because they were fraudulent or issued by a non-licensed pharmacy. Alternatively, these Defendants knew or had reason to know that Medicare would not pay claims submitted to it if these programs knew that Eco Apothecary or any of the Defendants was unlicensed and the prescriptions they dispensed were invalid as described.

FACTS

63. On or around June 4, 2008, Defendant Ammon pled guilty to health care fraud (18 U.S.C. § 1347) and making false claims to the United States (18 U.S.C. § 287). Ammon served seven and one-half months of a 366 day prison sentence. Ammon surrendered his Utah pharmacist license as a result of the judgment in his criminal case.

64. Following his release from federal prison, Ammon re-applied for his Utah pharmacist license in May, 2012. The State of Utah reinstated his license on September 20, 2012, license number 259975-1701.

65. On around January 13, 2016, Eco Pharmacy opened and began business operations. Ammon began working for Eco Pharmacy on around December, 2016.

66. On around February 6, 2018, Eco Apothecary opened and began business operations.

67. Eco Pharmacy surrendered its DEA registration to dispense controlled substances on October 17, 2018.

68. Eco Pharmacy appears to have closed its physical location sometime in September, 2018.

69. On August 14, 2018, DEA and the State of Utah conducted a routine audit of the Eco Apothecary specialty pharmacy located at 3702 S. State Street, Suite 117, Salt Lake City, Utah 84115. Also on August 14, 2018, the DEA conducted an audit of Eco Pharmacy located at 12523 Creek Meadow Road #105, Riverton, Utah 84065.

70. During the audits, the DEA reviewed a variety of records of the dispensing of controlled substances by Eco Apothecary and Eco Pharmacy. At the same time, the DEA investigators interviewed a number of the Eco Apothecary and Eco Pharmacy staff personnel who were present at the locations inspected.

71. DEA reviewed the records during the audit of Eco Apothecary and Eco Pharmacy. Upon concluding its review and audit, DEA determined that each of Eco Apothecary and Eco Pharmacy had been operating its business in violation of federal laws and regulations.

72. In addition to the DEA and State of Utah inspections, the FBI and HHS-OIG at around the same time as the inspections began to investigate Eco Apothecary, Eco Pharmacy, and James Ammon. They interviewed patients and medical providers, and reviewed claims submitted to Medicare and Medicaid for payment. Their investigation revealed several violations of the FCA.

73. Eco Apothecary's State-held license expired on September 30, 2019. Eco Apothecary applied for renewal of its license in late-September, 2019. The Utah Division of Occupational and Professional Licensing ("DOPL") denied Eco Apothecary's license renewal, meaning Eco Apothecary did not have a valid Utah license to operate a pharmacy and dispense medication after September 30, 2019.

74. DOPL found the following grounds for denying Eco Apothecary's license renewal:

A. Between February 20, 2018 and July 12, 2019, it "dispensed no less than two hundred sixty-five (265) prescriptions which were not timely reported to the Utah Controlled Substances Database ("CSD")." The failure to timely report prescriptions to the Utah Controlled Substances Act is a violation of state law which requires real-time submission. *See* Utah Code Ann. § 58-37f-203. In many instances, Eco Apothecary delayed reporting controlled substances to the CSD for over 100 days and in other instances over 200 days;

B. Failure to have a pharmacist-in-charge and provide information on the pharmacist-in-charge to DOPL;

C. Failure to inform DOPL of a change of location when Eco Apothecary moved to a suite next door (suite 115) to the one listed on its license application (suite 117); and

D. Providing misinformation on the renewal application, including the social security number that did "not match any person on file with the Division, nor . . . any licensee representing Eco Apothecary, LLC." The social security number provided later was found to match a deceased woman from Florida.

DEFENDANTS' CSA VIOLATIONS

75. Virtually from the day it opened until present, Eco Apothecary has violated numerous provisions of the CSA (*e.g.*, 21 U.S.C. §§ 842(a)(1) & (a)(5)) as set forth hereinafter:

A. In violation of 21 C.F.R. § 1304.21(a), 21 U.S.C. § 827(a)(3), Eco Apothecary did not have complete and accurate dispensing and receiving records for Schedules

II-V controlled substances based on four discrepancies found during the accountability audit of seven controlled substances.

B. In violation of the requirements of 21 CFR § 1304.11(b), 21 USC § 827(a)(1), Eco Apothecary did not provide records of an initial inventory from when Eco Apothecary first engaged in the dispensing of controlled substances. The State of Utah, during a routine inspection did locate an initial inventory taken on March 7, 2018, but it was never signed by the pharmacist-in-charge. The initial inventory was signed only by Defendant James Ammon. Mr. Ammon attested that Eco Apothecary "had zero inventory" of Schedule II-V medications "at opening." The State, in reviewing controlled substance records (ARCOS report), found that controlled substances had been purchased by Eco Apothecary prior to March 7, 2018. Eco Apothecary had no records reflecting the purchase of controlled substances prior to March 7, 2018.

C. In violation of 21 CFR § 1305.13(e), 21 USC § 828(a), Eco Apothecary did not properly indicate the number of packages received and the date it received them on one DEA-222 Order Form for Schedule II controlled substances.

D. In violation of 21 CFR § 1304.21(d), 21 USC § 827(b)(1), Eco Apothecary did not record the date of receipt on purchase invoices for eight Schedule III-V purchases.

E. In violation of 21 CFR § 1317.40(a), 21 CFR § 1301.51(b), Eco Apothecary and Eco Pharmacy failed to provide or furnish a modified registration authorizing them to participate in collection activities. Eco Apothecary in particular illegally collected medications and re-distributed end-user controlled substances as shown by several plastic bins

filled with various containers of partial empty end-user controlled substance prescriptions, and numerous pills found in unlabeled prescription bottles by DEA diversion investigators during their audit.

F. In one specific instance, employees of Eco Pharmacy found 60 to 65 tablets of Morphine, a controlled substance, in a patient's old prescription disk that the Pharmacy had collected from the patient. The employees placed the tablets in a bottle and set them aside because they were not sure how to handle them. The next morning the tablets were missing and it is believed that Mr. Ammon or another employee at the pharmacy resold the pills or, as was customary, threw them in a large plastic bin with other miscellaneous medications.

76. Virtually from the day it opened until the day it surrendered its DEA registration, Eco Pharmacy violated numerous provisions of the CSA's record keeping requirements (21 U.S.C. § 842(a)(5)) as set forth hereinafter:

A. In violation of 21 C.F.R. § 1304.11(c), 21 U.S.C. § 827(a)(1), Eco Pharmacy had no Biennial Inventory for Schedule II controlled substances.

B. In violation of 21 C.F.R. § 1305.12(d), 21 U.S.C. § 827(a)(1), Eco Pharmacy had no power of attorney in 46 instances where DEA-222s were signed by individuals not authorized to sign.

C. In violation of 21 C.F.R. § 1305.13(e), 21 U.S.C. § 827(a)(1), Eco Pharmacy did not properly indicate the number of packages received and the date it received them on and failed to include other required information on 2 DEA-222 order forms for Schedule II controlled substances.

D. In violation of 21 C.F.R. § 1305.17(c), 21 U.S.C. § 828(c)(1), Eco Pharmacy was missing DEA-222 order forms, numbers 172922907, 17922935, 172922912, 172922941, 172922920 and 172922940.

E. In violation of 21 C.F.R. § 1305.17(c), 21 U.S.C. § 828(c)(1), Eco Pharmacy did not maintain six DEA-222 order forms for 2 years.

F. In violation of 21 C.F.R. § 1304.04(a), 21 U.S.C. § 827(b)(3), Eco Pharmacy did not keep or maintain one receiving record for 2 years.

G. In violation of 21 C.F.R. § 1306.05(a), 21 U.S.C. § 827(b)(1), Eco Pharmacy improperly filled or dispensed 25 prescriptions for Schedule II controlled substances that failed to contain all required information. Eco Pharmacy had a corresponding responsibility to make sure all prescriptions it filled met the requirements of the CSA.

H. In violation of 21 C.F.R. § 1306.21(a), 21 U.S.C. § 827(b)(1), Eco Pharmacy improperly filled or dispensed 23 prescriptions for Schedule III-V controlled substances that failed to contain all required information. Eco Pharmacy had a corresponding responsibility to make sure all prescriptions it filled met the requirements of the CSA.

I. In violation of 21 C.F.R. § 1305.17(c), 21 U.S.C. § 828(c)(1), Eco Pharmacy did not have the completed seller's copy of DEA-222 order form, number 180151878. A pharmacy must maintain and keep DEA-222 Order Forms for 2 years. In addition, Eco Pharmacy and Eco Apothecary moved controlled substances between them without invoices or DEA-222 order forms. Typically Eco Pharmacy would order controlled substances and then divide the order with Eco Apothecary without any supporting documentation required by the DEA.

77. In addition to the record keeping violations, virtually from the day the pharmacies opened, Defendants violated the CSA by dispensing controlled substances in violation of a pharmacist's corresponding responsibility, 21 C.F.R. § 1306.04(a), and outside the usual course of pharmacy practice, 21 C.F.R. § 1306.06 as set forth hereinafter:

A. Ammon and Eco Apothecary dispensed medications for controlled substances for which there was not a valid prescription or authorization. Ammon and individuals acting under his supervision either created prescriptions themselves, forged the name of prescribing health care providers or otherwise created an authorization for prescriptions that were not authorized by a licensed medical provider.

B. Ammon and individuals acting under his supervision while acting in the scope of their employment created or forged prescriptions for and then dispensed medications to unsuspecting Medicare beneficiaries.

78. Although it is entirely unclear how many bogus prescriptions Defendants filled, it is believed based on available information that they filled in excess of 100 bogus prescriptions in violation of the Controlled Substance Act.

79. Defendants violated the CSA each time they filled or dispensed an invalid prescription because:

A. They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1).

B. They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. 1306.06, and therefore such

dispensing and delivering of controlled substances was not authorized by the CSA, and thereby violated 21 U.S.C. § 841(a).

DEFENDANTS' FALSE CLAIMS ACT VIOLATIONS

80. Plaintiff United States of America's investigation of Defendants' practices found the following FCA violations:

A. Defendants caused Medicare to pay for medications Defendants never dispensed. Eco Apothecary and James Ammon billed and caused Medicare to pay for the prescriptions of one patient who received at least 10 separate medications on a regular basis from Eco Apothecary. The patient was supposed to receive a delivery from Eco Apothecary every two weeks containing a 28 day supply of medication. Many of these medications were anti-rejection medications because the customer was a liver and kidney transplant recipient. In mid-December 2019, the patient did not receive the scheduled shipment of medications. As a result, a relative visited Eco Apothecary's physical location but was unable to contact anyone but left a note on the door. He was never contacted by anyone at Eco Apothecary. When trying to fill these medications at another pharmacy, the patient was told that they could not be filled because "insurance" had already paid the claim. Eco Apothecary also caused Medicare to pay for alcohol swabs and a nasal spray the patient never received. Eco Pharmacy employees reported finding repeated instances where a customer had never actually received medications that had been billed to insurance or Medicare.

B. Defendants caused Medicare to pay for medications dispensed pursuant to forged prescriptions and authorizations. Eco Apothecary and Ammon caused Medicare to pay for three Basaglar Kwikpen (insulin) prescriptions, each with five refills even though Eco

Apothecary only delivered one of the prescribed fills to patients. It appears Ammon created the prescription himself, forged the name of the physician, and "created" refills that were not authorized by a licensed medical provider. The prescriptions themselves are also lacking required information such as a patient addresses in violation of Federal regulation. Based on this example and the records it has reviewed, the United States believes Ammon and Eco Apothecary acted similarly with many other patients and medications.

C. Defendants caused Medicare to pay for medications that had no valid prescription. Ammon and Eco Pharmacy had a practice of placing prescriptions on "auto re-fill" which had the effect of Eco Pharmacy dispensing medications and billing Medicare for medications that were never actually prescribed or medications that had an old, outdated dosage. Ammon and Eco Pharmacy filled prescriptions for one patient, a Medicare beneficiary, for nearly one year without a valid prescription. In the example of this patient, Ammon produced a list of prescriptions the beneficiary was receiving in a meeting with the beneficiary. Sometime after dozens of prescriptions had been dispensed without a valid prescription, a new pharmacist hired by Eco Apothecary realized there was no valid prescriptions and contacted the medical providers in an attempt to obtain valid prescriptions. The prescriptions Eco Apothecary filled and billed Medicaid for included dangerous controlled substances such as Gabapentin, Metoprolol, Valsartan, Clonidine, and Amlodipine.

D. Defendants caused Medicare to pay for medications not prescribed or requested by patients. Several Medicare beneficiaries requested Eco Apothecary and Eco Pharmacy stop sending medications because the patients had discontinued using the medication,

yet Eco Apothecary continued to send the medications and bill Medicare. These medications included insulin pens, Valganciclovir, Basaglar (insulin), and others.

E. Defendants caused Medicare to pay prescriptions Eco Apothecary filled using Eco Pharmacy's DEA registration number. On multiple occasions, Ammon and Eco Apothecary used Eco Pharmacy's DEA registration number to bill Medicare for prescriptions Eco Apothecary dispensed.

F. Defendants caused Medicare to pay for prescription refills where no refill prescription or authorization existed. Defendants created refill authorizations or prescriptions and refilled, dispensed, and billed Medicare for medications that did not have a valid refill. For example, Defendants caused Medicare to pay for dozens of one patient's prescription of Valganciclover that had only one fill, and no refills. When the patient discontinued this medication, Eco Pharmacy and Ammon billed Medicare for additional refills that were never delivered to the patient. The refill requests appear to be forged by Ammon, authorized by a doctor the patient never saw, and created after the patient discontinued the medications.

81. Defendants' dispensing of medications to Medicaid beneficiaries appears to follow the same improper pattern and practices detailed in paragraphs 77-80. More specifically, Defendants dispensed prescriptions without a legitimate medical purpose and outside the usual course of professional practice and knowingly submitted false claims to Medicare for the bogus prescriptions it dispensed and for medications it never actually dispensed.

82. Both Eco Apothecary and Eco Pharmacy participated in programs of Medicare Part D Plan Sponsors at all material times. Upon information and belief, Defendants schemed to

obtain substantial, improper reimbursements for controlled substances and other medications from the Medicare program.

83. From 2018 through 2019, Eco Apothecary and James Ammon caused Medicare Part D Plan Sponsors to pay at least $1,662,077 for prescriptions they dispensed.

84. From 2018 through 2019, Eco Pharmacy and James Ammon caused Medicare to pay at least $1,895,264 for prescriptions they dispensed.

85. Eco Apothecary and Ammon caused Medicare and Medicaid Plan Sponsors to pay at least $274,129 and Medicaid at least $11,013 for at least 2576 prescriptions after September 30, 2019, the date it was no longer licensed by the State of Utah to operate as a pharmacy and dispense medication.

86. Because many of the prescriptions dispensed by Eco Apothecary and Eco Pharmacy were not valid prescriptions that complied with federal law and were not issued for a legitimate medical purpose or for a medically accepted indication, Medicare would not have paid for the tainted Part D controlled substances medications during the applicable period if Medicare had known that the prescriptions were illegitimate and invalid.

87. Because several prescriptions dispensed, or caused to be dispensed, by Defendants lacked a legitimate medical purpose, were not for a medically accepted indication, and did not constitute valid prescriptions under federal law at relevant times, Medicare also would not have paid for those Part D medications during the applicable periods.

88. Despite Defendants' knowledge, reckless disregard, or deliberate ignorance of the fact that they were unlawfully dispensing medications pursuant to prescriptions Ammon created

with provider signatures he created or forged, Defendants knowingly made, or caused to be made, and received and retained payments from Medicare for false and fraudulent claims.

COUNT I
Unlawful Record Keeping: 21 U.S.C. §§ 827 & 842(a)(5)
Civil Penalties

89. The United States repeats and realleges Paragraphs 1 through 88 as if fully set forth herein.

90. Defendants refused or negligently failed to make, keep, or furnish records, reports, orders or order forms, and invoices required by the CSA in violation of 21 U.S.C. §§ 842(a)(5).

91. As a result of the foregoing violations, Defendants are liable to the United States for civil penalties in the amount of not more than $15,040 for each violation pursuant to 21 U.S.C. § 842(c)(1)(B) and 28 C.F.R. § 85.5.

COUNT II
Unlawful Dispensing: 21 U.S.C. §§ 829, 842(a)(1), 842(c)(1)(A)
Civil Penalties

92. The United States repeats and realleges Paragraphs 1 through 91 as if fully set forth herein.

93. Defendants dispensed controlled substances outside the usual course of professional pharmacy practice in violation of the CSA, 21 U.S.C. § 842(a)(1).

94. As a result of the foregoing violations, Defendants are liable to the United States for civil penalties in the amount of not more than $64,820 for each violation pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT III
False or Fraudulent Claims to Medicare and Medicaid in Violation of 31 U.S.C. § 3729(a)(1)(A)

95. The United States incorporates by reference the allegations contained in paragraphs 1 through 94.

96. Defendants knowingly, or with reckless disregard, presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). Specifically, Defendants submitted, or caused Eco Apothecary and Eco Pharmacy to submit requests for payment to Part D Plan Sponsors for controlled substance medications that were not dispensed for a legitimate medical purpose under the CSA, that were dispensed without a valid prescription, or were never issued to the patient when those claims were not payable.

97. The United States paid more money to the Medicare Part D Plan Sponsors than they would have based upon the mistaken belief that the Sponsors reimbursed pharmacies for drugs that were dispensed for a legitimate medical purpose, for a medically accepted indication, and upon a valid prescription that thus were covered under the Medicare Part D Program. The United States would not have paid for the drugs had it known the true facts.

98. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $11,181 to $22,363 per violation.

COUNT IV
Injunctive Relief, 18 U.S.C. § 1345

99. The United States repeats and realleges Paragraphs 1 through 98 as if fully set forth herein.

100. Defendants have presented or caused to be presented false and fraudulent claims upon the United States and upon the State of Utah in violation of 18 U.S.C. § 287.

101. Defendants' fraud upon the United States constitutes a continuing and substantial injury to the United States and its citizens.

102. The United States brings this action to protect Medicare funds by restraining defendants' unlawful fraudulent conduct and to protect and restrain the transfer of funds and assets now in defendants' hands as ill-gotten gains from their fraud upon the Medicare program.

103. Upon a showing of probable cause to believe that defendants are violating 18 U.S.C. § 287, the United States is entitled, under 18 U.S.C. § 1345, to a temporary restraining order, a preliminary injunction, a permanent injunction restraining future fraudulent conduct and any other action which this Court deems just in order to prevent a continuing and substantial injury to the United States. This relief may include an order freezing defendants' assets that are the product of, or profit on the product of, their fraud.

COUNT V
Injunction, 21 U.S.C. §§ 841, 842

104. The United States incorporates by reference the allegations contained in paragraphs 1 through 103.

105. In addition to civil monetary penalties for violations of the CSA and treble damages for violations of the FCA, the CSA authorizes injunctive relief to enjoin Defendants

and those acting in concert and participation with them from continuing to unlawfully dispense prescription medications in order to protect the public from any further harm caused by Defendants' conduct.

106. Defendants jointly, acting in concert and participation with one another, and through their agents and employees, have repeatedly violated 21 U.S.C. § 842(a)(1), in that they knowingly dispensed controlled substances without a valid prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice pursuant to 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a).

107. Defendants jointly, acting in concert and participation with one another, and through their agents and employees, have repeatedly violated in 21 U.S.C. § 841(a)(1) in that they repeatedly knowingly and intentionally distributed and dispensed controlled substances while not acting in the usual course of the professional practice of a pharmacy, pursuant to 21 C.F.R. § 1306.06.

WHEREFORE, plaintiff, United States of America, respectfully requests that the Court:

A. Enter an order requiring Defendants to pay a civil penalty of $64,820, pursuant to 21 C.F.R. § 85.5, for each individual prescription that was filled in violation of 21 U.S.C. § 842.

B. Enter an order requiring Defendants to pay a civil penalty of $15,050, pursuant to 21 C.F.R. § 85.5, for each violation of 21 U.S.C. § 842(a)(5).

C. Enter an order for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper for each violation of 31 U.S.C. § 3129;

D. Enter an order enjoining Defendants and each of their officers, agents, servants, employees, representatives, successors, and assigns from directly or indirectly distributing, dispensing, or possessing with the intent to distribute, or dispense, any controlled substances as defined and identified in 21 U.S.C. §§ 802(6) and 812, and 21 C.F.R. §§ 1308.11 through 1308.15; and

E. Such other proper relief to which it is entitled.

Respectfully submitted this 24th day of February, 2020.

JOHN W. HUBER
United States Attorney

/s/ Joel A. Ferre
JOEL A. FERRE
Assistant United States Attorney